## **Quality standards**

Edition: BP 2025 (Ph. Eur. 11.6 update)

# **Calcium Carbonate Oral Suspension**

#### **General Notices**

NOTE: This monograph has been developed to cover unlicensed formulations.

#### Action and use

Phosphate binder; treatment of hyperphosphataemia.

### **DEFINITION**

Calcium Carbonate Oral Suspension is a suspension of Calcium Carbonate in a suitable vehicle.

The oral suspension complies with the requirements stated under <u>Oral Liquids</u> and with the following requirements. Where appropriate, the oral suspension also complies with the requirements stated under Unlicensed Medicines.

#### Content of calcium carbonate, CaCO<sub>3</sub>

90.0 to 110.0% of the stated amount.

#### **IDENTIFICATION**

It may be necessary to add a drop of a suitable antifoaming agent to a volume of the oral suspension before carrying out the following tests.

- A. Mix 1 volume of the oral suspension with 1 volume of <u>water</u> and filter. The filtrate yields reaction C characteristic of *calcium salts*, Appendix VI.
- B. Dilute a volume of the oral suspension containing 0.6 g of Calcium Carbonate to 2 volumes with <u>2M hydrochloric acid</u>. The resulting solution yields reaction A characteristic of *carbonates*, Appendix VI.

### **TESTS**

#### **Acidity or alkalinity**

pH 7.0 to 8.7, Appendix V L.

#### Dissolution

Complies with the requirements stated under Unlicensed Medicines, Oral Suspensions. Use a volume of the oral suspension containing one dose.

#### **ASSAY**

It may be necessary to add one or two drops of a suitable antifoaming agent to the oral suspension before carrying out the Assay.

To a weighed quantity of the oral suspension containing 0.15 g of Calcium Carbonate add 3 mL of <u>dilute hydrochloric acid</u> and 20 mL of <u>water</u>. Boil for 2 minutes, allow to cool and dilute to 50 mL with <u>water</u>. Carry out the <u>complexometric titration</u>

https://nhathuocngocanh.com/bp/of calcium, Appendix VIII D. Determine the weight per ml of the oral suspension, Appendix V G, and calculate the content of CaCO<sub>3</sub>, weight in volume.

Each mL of  $\underline{\textit{0.1M sodium edetate}}$  is equivalent to 10.01 mg of CaCO<sub>3</sub>.